



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 1997

Vipin D. Shah
• Chief Operating Officer
Consolidated Technologies, Inc.
2170 Woodward Street
Austin, Texas 78744-1832

Re: K972080
Qualitrol DHP Immunoassay Control Levels 1, 2, and 3
Regulatory Class: I
Product Code: JJY
Dated: May 31, 1997
Received: June 3, 1997

Dear Mr. Shah:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

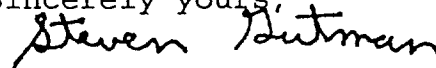
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

* If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

Device Name: Qualitrol DHP Immunoassay Control
CONFORMANCE MCC-Ligand Control

Indication for Use: Clinical laboratories, performing immunoassays for drugs, hormones and proteins on automated immunoassay systems may use Qualitrol Immunoassay DHP Control or CONFORMANCE MCC-Ligand Control routinely as a means of estimating precision and monitoring test system performance, provided:

(a) the above mentioned controls, provided as a set (Levels 1, 2 and 3) are used as an adjunct to primary control procedure recommended by the manufacturer of immunoassay systems.

(b) above mentioned controls are used in accordance with the quality control requirements of regulatory and/or accrediting organizations and laboratory's quality control goals;

(c) above mentioned controls are validated for use with the specific immunoassay test system being used by the clinical laboratory.

These controls have been assayed with AxSYM, IMx and TDX systems manufactured by Abbott Laboratories (Abbott Park, USA). The expected values, for these systems, are included in the package insert. The controls may be used as assayed controls for the stated indication for use when measurements are made with above-mentioned immunoassay systems.


(Division Sign-Off)

Division of Clinical Laboratory Devices

310(k) Number

5972080

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Qualitrol DHP Control

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